EXEMPTION & EXPEDITED REVIEW

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IRB Review Categories

- Exemption : Does not require initial or continuing review by IRB
- Expedited : Review by 2 reviewers
- Full Board

EXEMPTION

1. Educational researches e.g. adjustment of teaching methods of the entire class
2. Applied research protocols on educational evaluation
3. Research on known results (published or public data)
4. Research related to micro-organisms : not related to identifiable personal identity
5. Commercially cell lines

EXEMPTION (cont.)

6. Research on policies, strategies under the approval of the institues
7. Research on flavor, quality of food
8. Not involve living human : phantom, cadavers
9. Case(s) report : not more than 3 cases

COE No. 000/0000

IRB No. 000/00

INSTITUTIONAL REVIEW BOARD

Faculty of Medicine, Chulalongkorn University

1873 Rama IV Road, Patumwan, Bangkok 10330, Thailand, Tel 662-256-4493

Certificate of Exemption

The Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, has exempted the following study in compliance with the International guidelines for human research protection as Declaration of Helsinki, The Belmont Report, CIOMS Guideline, International Conference on Harmonization in Good Clinical Practice (ICH-GCP) and 45CFR 46.101(b)

Study Title :

Study Code :

Principal Investigator :

Affiliation of PI :

Document Approval :

1.

Signature: ..... Signature: .....

( ) ( )

Chairperson
The Institutional Review Board

Member and Secretary
The Institutional Review Board

Date of Exemption :

Note No continuing review report and final report when finish required

EXEMPTION

Continuing review report and final report are NOT required

EXPEDITED REVIEW

- Not more than minimal risk

The probability and magnitude of harm or discomfort anticipated in the research are *not greater* in and of themselves *than those ordinarily encountered in daily life* or *during the performance of routine physical or psychological examinations or tests*

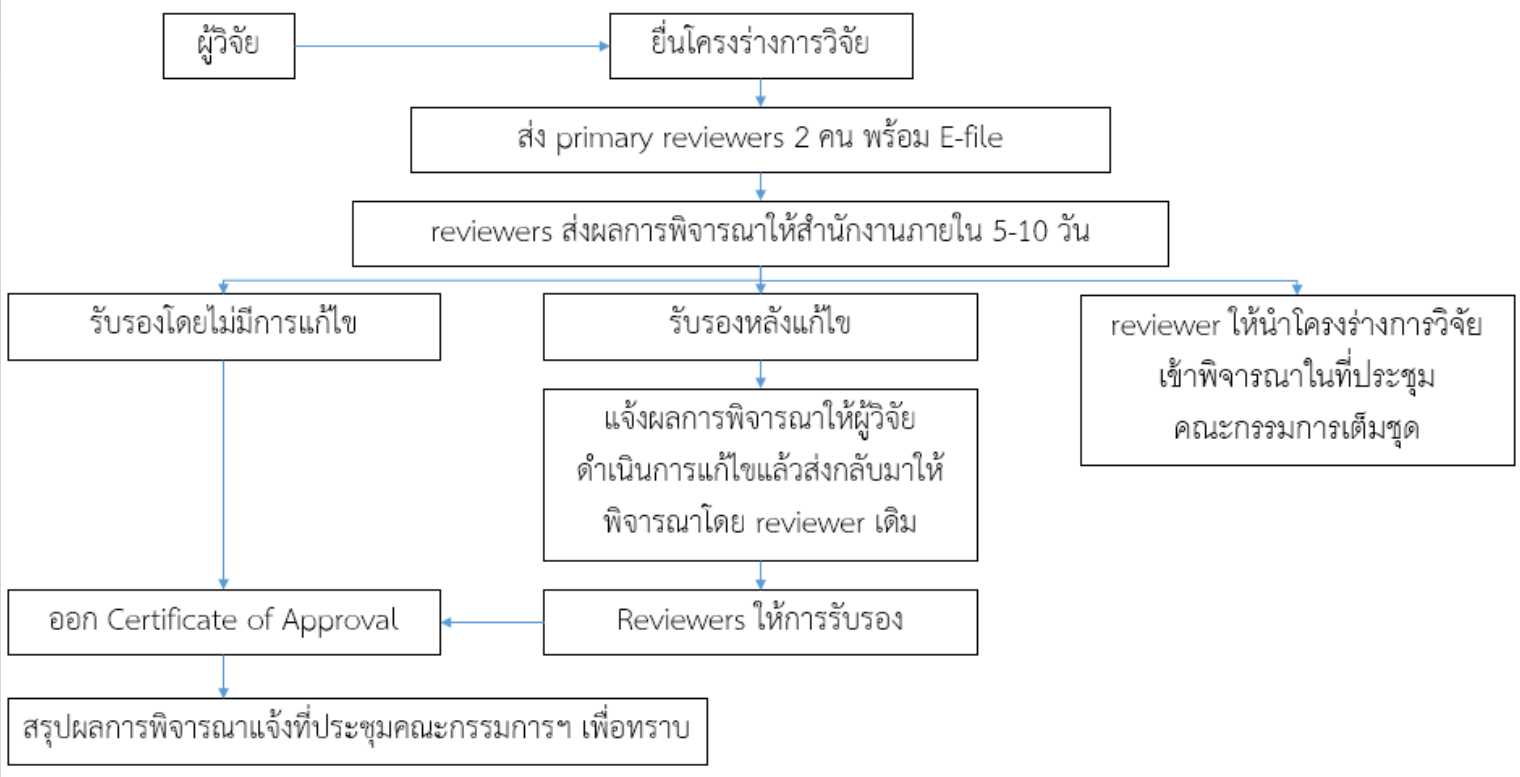
EXPEDITED REVIEW

- Collection of blood samples by venipuncture
  - Healthy 550ml / 8 wk, not more than 2/wk
  - Children not exceed 50ml or 3ml/kg
- Noninvasive collection of specimens eg. Nail clipping, buccal swab
- Noninvasive procedures routinely employed in clinical practice eg. EKG, ultrasound

EXPEDITED REVIEW

- Examining data, records, documents, specimens
- collected for non-research purposes
- Survey, interview, or focus-group research
- Continuing review
- Minor changes

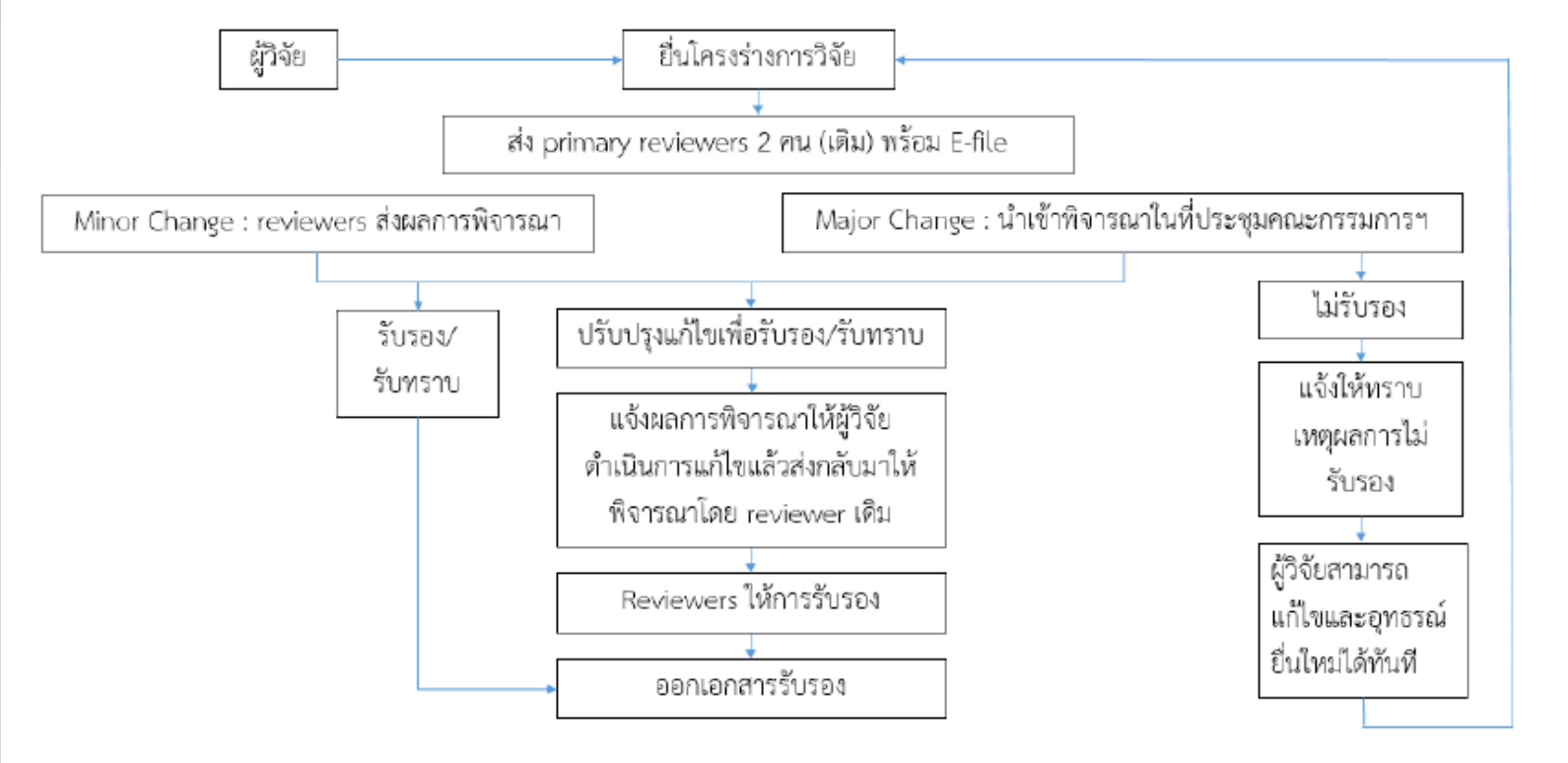
EXPEDITED REVIEW



AFTER INITIAL APPROVAL

- Protocol amendments
- Progress report
- SAE
- Protocol deviation/violation/non-compliance
- Final report
- Termination
- Site visit

PROTOCOL AMENDMENTS

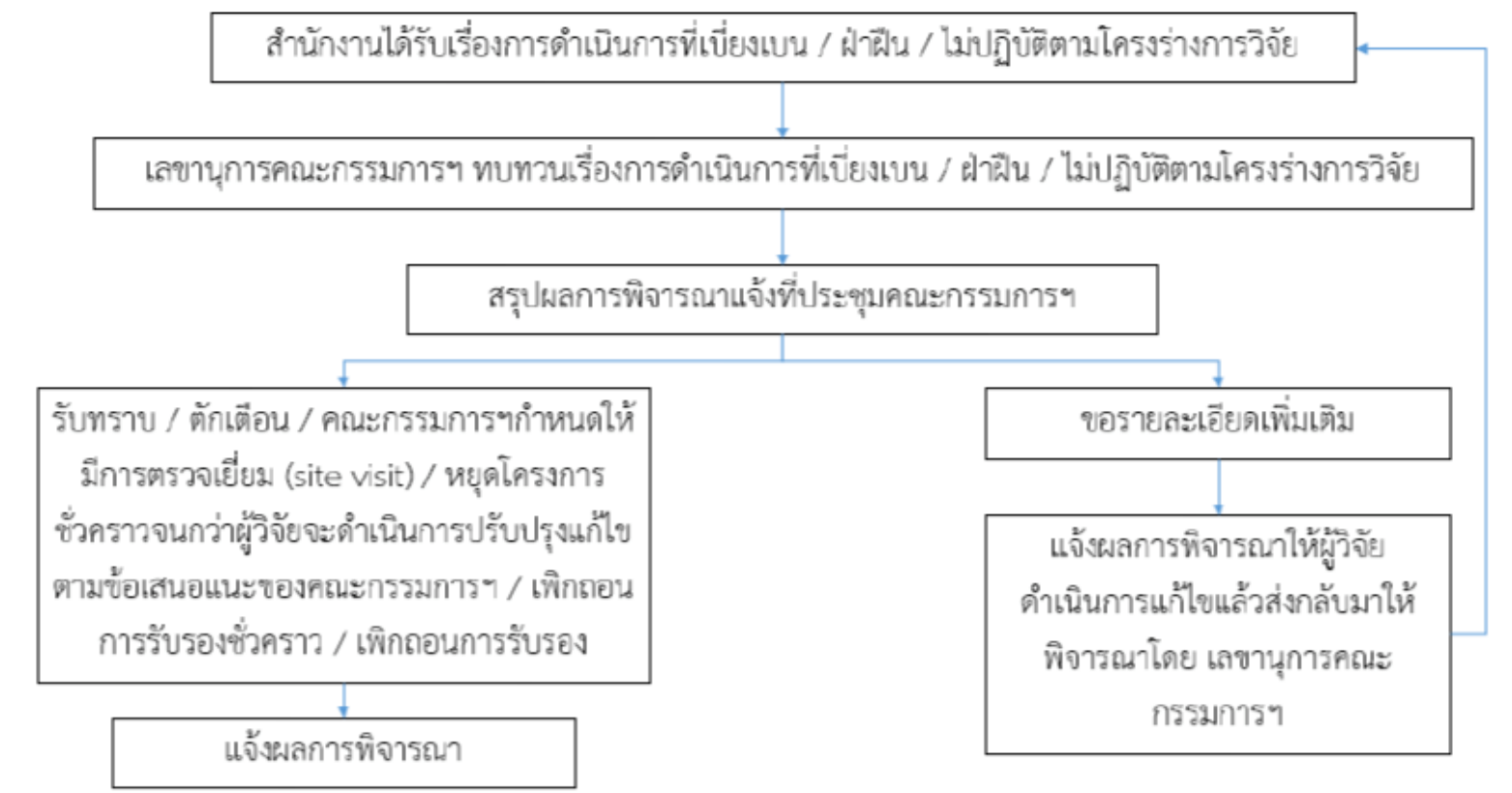


Amendment	☐ Protocol ☐ Minor changes ☐ Major changes	☐ ICF	☐ IB	☐ Others	
Descriptive summary of the amendment :					
Justification for using expedited review process:		☐ Yes	☐ No		
appropriate inclusion/exclusion criteria:		☐ Yes	☐ No	☐ N/A	
acceptable risk/benefit ratio:	risk	☐ increased	☐ same	☐ decreased	
	benefit	☐ increased	☐ same	☐ decreased	
adequate consent form:		☐ Yes	☐ No	☐ N/A	
approval/acknowledge :		☐ acknowledge (การเปลี่ยนแปลง IB)			
		☐ approved			
		☐ approved with some correction			
		☐ full-board review needed			

PROGRESS REPORT

- Every 3 months, 6 months or yearly
- COA renewal?

Protocol deviation / violation / non-compliance



FINAL REPORT

Study site(s) :	
Objectives(s) :	
Study materials :	
Study dose(s) :	
Treatment form :	
Duration of the study :	
Total Number of study participants :	No. of Study Arms :
Number of participants recruited in the study :	
Number of dropout participants in the study :	
Number of SAE/SUSARs occurred :	
Number of Non-Compliance / Protocol violation occurred:	
Post trial access to study drug :	
Brief summary of the result :	

STUDY TERMINATION

- Reasons : Risk/benefit of participants, other reasons (financial, enrollment,…)
- Summary of results
- Management of participants

Questions / Comments